

1982 WL 189206 (S.C.A.G.)

Office of the Attorney General

State of South Carolina

March 15, 1982

\*1 The Honorable H. Parker Evatt  
House of Representatives  
Post Office Box 11867  
Columbia, South Carolina 2911

Dear Representative Evatt:

You have requested an opinion of this Office as to whether 21 CFR Part 201 may be used to further define the term 'manufacturer' in [§ 39-23-40 of the 1976 CODE OF LAWS OF SOUTH CAROLINA](#), as amended.

As I understand the situation; Miles Laboratories, Inc., of West Haven, Connecticut, wishes to distribute in this State a new prescription drug, Mezlin (mezlocillin sodium), which is manufactured by, among others, an affiliated German company, Bayer Aktiengesellschaft. Miles expects to have its own manufacturing facility completed in approximately twelve to fourteen months after which time they would distribute Mezlin of their own manufacture. In the meantime, you relate that Miles is in apparent violation of [§ 39-23-40](#) which, in pertinent part, requires that the package label 'contain the name and place of business of the manufacturer of the finished dosage form and, if different, the name and place of business of the packer or distributor.' The label currently used by Miles bears no reference to the manufacturer, Bayer Aktiengesellschaft, in apparent violation of State law.

Since the term 'manufacturer' is not defined in Title 39, Chapter 23, it must be accorded its common meaning of one who by labor, art, or skill transforms raw materials into some kind of a finished product or article of trade. [Henry v. Markesan State Bank](#), 68 F. 2d 554, 557 (8th Cir., 1934).

However, you enclose a copy of the [Federal Register](#), 1/13/81, p. 2977, ff., which contains a notice of changes in 21 CFR Part 201 concerning the labeling of prescription drugs under federal law. That Federal Register notice merely stayed the effective date of proposed regulatory provisions concerning 'the actual corporate name' of the manufacturer in order to permit consideration of industry proposals allowing a broader interpretation of the term. To our knowledge, the matter has not been decided and, therefore, cannot be considered to support the broader industry view at this time.

Accordingly, it is the opinion of this Office that 21 CFR Part 201 may not be used to further define the term 'manufacturer' in [§ 39-23-40 of the 1976 CODE OF LAWS OF SOUTH CAROLINA](#), as amended.

I trust that the proceeding discussion adequately answers your question, however, if any further explanation or assistance is required, please do not hesitate to contact me.

Very truly yours,

Richard P. Wilson  
Assistant Attorney General

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